K000012

MAR - 3 2000

510 (k) Summary
Safety and Effectiveness

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: **Address:**	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, CA 90045
Telephone Number: **Facsimile Number:**	(310) 645-8200 (310) 645-9999
Contact Person:	Edward M. Levine, Ph.D. Director of Clinical Affairs
Date of Preparation:	December 27, 1999
Device Name: Trade:	IMMULITE® Phenobarbital
Catalog Number:	LKPB1 (100 tests), LKPB5 (500 tests)
CFR:	A phenobarbital test system is a device intended to measure phenobarbital, an antiepileptic and sedative-hypnotic drug, in human specimens. Measures obtained by this device are used in the diagnosis and treatment of phenobarbital use or overdose and in monitoring levels of phenobarbital to ensure appropriate therapy.
Common:	Reagent system for the determination of phenobarbital in serum or heparinized plasma.
Classification:	Class II device, 91-DLZ (21 CFR 862.3660)
Panel:	Toxicology
CLIA Complexity Category:	We believe the category to be moderate, based on previous classification of analogous tests.

Manufacturer:	Diagnostic Products Corporation (DPC) 5700 West 96th Street Los Angeles, CA 90045-5597
Establishment Registration #:	DPC's establishment Registration No. is 2017183
Substantially Equivalent Predicate Device:	Abbott AxSYM Phenobarbital (K940596)
Description of Device:	IMMULITE® Phenobarbital is a solid-phase, chemiluminescent enzyme immunoassay for use with the IMMULITE® Automated Analyzer.
Intended Use of the Device:	IMMULITE® Phenobarbital is for *in vitro* use with the IMMULITE Analyzer - for the quantitative measurement of phenobarbital in serum or heparinized plasma, as an aid in monitoring drug therapy.

Technology:

This section does not contain any new information for a reviewer who is familiar with the DPC IMMULITE® System based upon the review of previous IMMULITE® assay submissions.

IMMULITE® Phenobarbital is a solid-phase, chemiluminescent immunoassay. The solid phase, a polystyrene bead enclosed within an IMMULITE Test Unit, is coated with a polyclonal antibody specific for phenobarbital.

The patient sample and alkaline phosphatase-conjugated phenobarbital are simultaneously introduced into the Test Unit and incubated for approximately 30 minutes at 37°C with intermittent agitation. During this time, phenobarbital in the sample competes with the enzyme-labeled phenobarbital for a limited number of antibody binding sites on the bead. Unbound enzyme conjugate is then removed by a centrifugal wash, after which substrate is added and the Test Unit is incubated for a further 10 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple readings. The bound complex - and thus also the photon output, as measured by the luminometer - is inversely proportional to the concentration of phenobarbital in the sample.

Abbott AxSYM Phenobarbital utilizes fluorescence polarization immunoassay technology in a competitive ligand format. The unlabeled drug (antigen being measured) competes with the fluorescent-labeled antigen for the antibody binding sites. With increasing concentration of unlabeled antigen, more fluorescent-labeled antigen becomes unbound. Therefore, the fluorescent polarization signal decreases as the drug concentration increases, as measured by the fluorometer. Concentrations are determined from a stored standard curve.

Performance Equivalence:

Diagnostic Products Corporation asserts that the IMMULITE® Phenobarbital produces substantially equivalent results to other commercially marketed phenobarbital assays, such as Abbott AxSYM Phenobarbital. The Abbott AxSYM Phenobarbital assay utilizes fluorescence polarization technology. Each product is designed for the quantitative measurement of Phenobarbital in serum or plasma. Each product is intended strictly for in vitro diagnostic use as an aid in monitoring the therapeutic administration of this drug.

Method Comparison:

The IMMULITE Phenobarbital procedure was compared to a commercially available assay (Abbott AxSYM) on 47 patient samples, with phenobarbital concentrations ranging from approximately 6.2 to 70 µg/mL. Linear regression analysis yielded the following statistics.

(IMMULITE) = 0.99 (Abbott) + 1.04 µg/mL r = 0.995

Means: 29.4 µg/mL (IMMULITE)
28.5 µg/mL (Abbott)

Conclusion:

The data presented in this summary of safety and effectiveness is the data that the Food and Drug Administration used in granting DPC substantial equivalence for IMMULITE® Phenobarbital

Edward M. Levine 12/27/95

Edward M. Levine, Ph.D. **Date**
Director of Clinical Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 2000

Edward M. Levine, Ph.D.
Director of Clinical Affairs
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045-5597

Re: K000012
Trade Name: IMMULITE® Phenobarbital
Regulatory Class: II
Product Code: DLZ
Regulatory Class: I
Product Code: DIF
Dated: December 27, 1999
Received: January 3, 2000

Dear Dr. Levine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: **IMMULITE® Phenobarbital**

Indications For Use:

IMMULITE® Phenobarbital is for *in vitro* diagnostic use with the IMMULITE Analyzer - for the quantitative measurement of phenobarbital in serum or heparinized plasma, as an aid in monitoring drug therapy.

(Div. ...n-Off)
Divi... ...linical Labora...
510(...)...mber K000212

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)